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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,364	10/23/2000	Alexei Khomutov	933-160P	2717

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/623,364	<b>Applicant(s)</b> KHOMUTOV ET AL.	
	<b>Examiner</b> EVERETT WHITE	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 10,11 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,12-14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The amendment filed August 18, 2004 have been received, entered and carefully considered. The amendment affects the instant application accordingly:
  - (A) Claim 9 has been canceled;
  - (B) Claims 4, 5, 8, 16 and 17 have been amended.
  - (D) Comments regarding Office Action have been provided drawn to
    - (i) restriction requirement, which has been maintained in part;
    - (ii) 112, 2<sup>nd</sup> paragraph rejection, which has been withdrawn;
2. Claims 1-8 and 10-19 are pending in the case. Claims 10, 11 and 15 are withdrawn from consideration.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Specification***

The disclosure is objected to because of the following informalities: On page 10, line 31 of the specification, reference is made to Claim 7 which is improper. The specification should not recite claim numbers. In all occurrences in the specification, the term "karboxy" should be changed to - - carboxy - -. See, for example, page 10, lines 26 and 28.

Appropriate correction is required.

### ***Answer To Arguments With Traverse***

4. Applicant's election with traverse of Group I, Claims 1-7 and 12-14 in there response filed December 12, 2003 is acknowledged. The traversal is on the ground(s) that Groups I and III should be reunited at the very least according to the guidelines promulgated in PCT Administrative Instructions Annex B, Part 2, Examples Concerning Unity of Invention", which Applicants argue that the compound of Group I differs from the compound of Group II by having different substituents on the common structure. Applicants argue that when claims differ in this manner, unity of invention exists where there is a common structure and the different substituents in the Markush group do not change the utility of the claimed compound. Applicants also argue for the rejoining of

Group II with Group I on the grounds that when a claim is directed to a compound and another claim is directed to making that claimed compound, unity of invention exists between the two claims. Upon reconsideration, Claims 8 and 16 will be rejoined since allowable subject matter is indicated.

Applicants further argue that Claims 10 and 11 are directed to novel uses of the compound of the elected invention. This argument is not persuasive since Claims 10, 11 and 15 are directed to an oxime (Claim 10) and nucleotide or nucleoside pyrimidines or purines (Claims 11 and 15), which are different inventions from the instantly claimed aminooxy-cyclodextrin of the elected invention.

The requirement is still deemed proper and is therefore made FINAL.

***Reply To Final Must Include Cancellation***

5. This application contains Claims 10, 11 and 15 are drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Claim Rejections - 35 USC § 112***

6. Claims 1-8, 12-14 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, lines 7 and 8, the claim recites that the aminooxy-cyclodextrin compounds "optionally carries further substituents different from (X-Y-ONH<sub>2</sub>) in their 6-, 3-, and/or 2-positions" without disclosing the substituents applicants are referring to, which renders the claim indefinite. In the absence of the specific substituents the claim is referring to or distinct language to describe the structural modifications of this invention, the identity of said substituents would be difficult to describe and the metes and bounds of said substituents that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 1, line 16, in the absence of the specific “aminoxy protected derivatives” of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 3, lines 2 and 3, the phrase “one or more of the primary hydroxyl groups at a 6-position of  $\alpha$ -,  $\beta$ -,  $\gamma$ -CD ” lacks clear antecedent basis since primary hydroxyl groups at the 6-position has not been previously recited. Claim 3 may be redundant since Claim 1 has already mentioned that a X-Y-ONH<sub>2</sub> group is a substituent at the 6-position.

In Claim 4, line 6, the claim recites that “aryl may be substituted” without disclosing the substituted groups, which renders the claim indefinite since the substituted groups have not been disclosed.

In Claim 4, lines 5 and 7, in the absence of the specific fragments to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of the arylalkylene fragments (line 5) or alkylene, alkenylene and alkynylene fragments (line 7) of this invention, the identity of said fragments would be difficult to describe and the metes and bounds of said fragments that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 7, lines 2 and 3, the phrase “one or more of the primary hydroxyl groups at 6-, 3-, and/or 2-positions” lacks clear antecedent basis since primary hydroxyl groups at the 6-, 3-, and/or 2-positions has not been previously recited.

In Claim 7, last line, the term “side chain” lacks clear antecedent basis since it has not been previously disclosed that the recited groups have side chains.

In Claim 8, line 9, the term “functional” lacks clear antecedent basis since this term has not been previously mentioned.

In Claim 8, line 21, the phrase “said substituent” lacks clear antecedent basis since it is not clear what substituent the claim is referring to.

In Claim 8, line 21, the claim recites "a substituent being in a protected form". There is no indication of how the substituent is protected, which renders the claim indefinite. For correction, it appears that lines 22 and 23 of Claim 8 should be deleted.

In Claim 8, line 32, the claim recites that "aryl may be substituted" without disclosing the substituted groups, which renders the claim indefinite since the substituted groups have not been disclosed.

In Claim 8, lines 31-34, in the absence of the specific fragments to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of the arylene or arylalkylene fragments (lines 31 & 32) or alkylene, alkenylene and alkynylene fragments (lines 33 & 34) of this invention, the identity of said fragments would be difficult to describe and the metes and bounds of said fragments that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 8, line 46, in the absence of the specific derivatizations to the chemical core claimed (thiol-, amino-, or carboxy- group) or distinct language to describe the structural modifications or the chemical names of derivatized thiol-, amino-, or carboxy-group of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 8, line 46, the term "functional" lacks clear antecedent basis since this term has not been previously mentioned in reference to a particular group.

In Claim 8, line 50, the term "side chain" lacks clear antecedent basis since it has not been previously disclosed that the recited groups have side chains.

In Claim 12, lines 2 and 3, in the absence of the specific derivatizations to the chemical core claimed (ethoxy-ethylidene or acetone oxime derivatives) or distinct language to describe the structural modifications or the chemical names of derivatized ethoxy-ethylidene or acetone oxime of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives that

Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Claim 16 is dependent from Claim 3 and refers to formula (3). However, Claim 16 and Claim 3 do not set forth a formula designated as formula (3), which renders Claim 16 indefinite.

In Claim 16, line 7, the term "functional" lacks clear antecedent basis since this term has not been previously mentioned in reference to a particular group.

In Claim 16, line 19, the phrase "said substituent" lacks clear antecedent basis since it is not clear what substituent the claim is referring to.

In Claim 16, line 19, the claim recites "a substituent being in a protected form". There is no indication of how the substituent is protected, which renders the claim indefinite. For correction, it appears that lines 20 and 21 of Claim 16 should be deleted.

In Claim 16, line 30, the claim recites that "aryl may be substituted" without disclosing the substituted groups, which renders the claim indefinite since the substituted groups have not been disclosed.

In Claim 16, lines 29-32, in the absence of the specific fragments to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of the arylene or arylalkylene fragments (lines 29 and 30) or alkylene, alkenylene and alkynylene fragments (lines 31 & 32) of this invention, the identity of said fragments would be difficult to describe and the metes and bounds of said fragments that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 16, line 44, in the absence of the specific derivatizations to the chemical core claimed (thiol-, amino-, or carboxy- group) or distinct language to describe the structural modifications or the chemical names of derivatized thiol-, amino-, or carboxy-group of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 16, line 44, the term "functional" lacks clear antecedent basis since this term has not been previously mentioned in reference to a particular group.

In Claim 16, line 48, the term "side chain" lacks clear antecedent basis since it has not been previously disclosed that the recited groups have side chains.

In Claim 17, lines 6-8, in the absence of the specific fragments to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of the arylene or arylalkylene fragments (line 6 ) or alkylene, alkenylene and alkynylene fragments (lines 7 & 8) of this invention, the identity of said fragments would be difficult to describe and the metes and bounds of said fragments that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 17, line 7, the claim recites that "aryl may be substituted" without disclosing the substituted groups, which renders the claim indefinite since the substituted groups have not been disclosed.

In Claim 17, line 10, the SO<sub>2</sub>- group should be changed to "-SO<sub>2</sub>-".

In Claim 18, line 3, in the absence of the specific derivatizations to the chemical core claimed (ethoxy-ethylidene or acetone oxime derivatives) or distinct language to describe the structural modifications or the chemical names of derivatized ethoxy-ethylidene or acetone oxime of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 19, line 4, the -OP(O)(OH) group should be changed to "-OP(O)(OH)O-".

Claims dependent from the rejected Claims above are also rejected.

7. Applicant's arguments with respect to claims 1-8, 12-14, 16 and 18 have been considered but are moot in view of the new ground(s) of rejection.



***Allowable Subject Matter***

8. The following is a statement of reasons for the indication of allowable subject matter: The reason for indicating allowable subject matter is that the prior art of record does not teach or fairly suggest an aminooxy-cyclodextrin of the formula 1 set forth in instant Claim 1 and aminooxy protected derivatives thereof. Upon reconsideration, it was agreed that the Varaprasad et al reference does not set forth an aminooxy protected derivative of an aminooxy-cyclodextrin compound.

9. Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

10. Claims 2-8, 12-14 and 16-19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Summary***

11. Claims 1-8, 12-14 and 16-19 are rejected; Claims 10, 11 and 15 are withdrawn from consideration as being directed to non-elected inventions.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Examiner's Telephone Number, Fax Number, and Other Information***

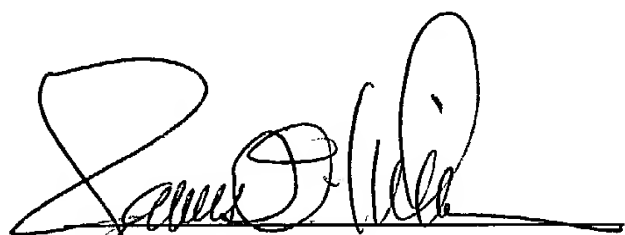
13. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
E.White

  
James O. Wilson  
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